



CSA C22.2 No. 60601-2-65:15

Medical electrical equipment — Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

(IEC 60601-2-65:2012+A1:2017, MOD)

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Appareils électromédicaux — Partie 2-65 : Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires intra-oraux

(IEC 60601-2-65:2012+A1:2017, MOD)



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Medical electrical equipment — Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment (IEC 60601-2-65:2012+A1:2017, MOD)

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CSA Preface

This is consolidated edition 1.1 of CAN/CSA-C22.2 No. 60601-2-65, *Medical electrical equipment — Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-2-65 (edition 1:2012 consolidated with Amendment 1:2017). It is one in a series of Standards issued by CSA Group under Part II of the *Canadian Electrical Code*.

For brevity, this Standard will be referred to as “CAN/CSA-C22.2 No. 60601-2-65” throughout.

This Standard is intended to be used in conjunction with CAN/CSA-C22.2 No. 60601-1:14, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* (adopted IEC 60601-1:2005, including Amendment 1:2012, with Canadian deviations).

Where differences exist between this consolidated edition and the published edition and its amendments, those documents will take precedence.

This Standard is considered suitable for use for conformity assessment within the stated scope of the Standard.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Consumer and Commercial Products, under the jurisdiction of the CSA Strategic Steering Committee on Requirements for Electrical Safety, and has been formally approved by the Technical Committee. Due to the medical content of this Standard, it was also approved by the CSA Technical Committee on Application of Electricity in Health Care under the jurisdiction of the CSA Strategic Steering Committee on Health Care Technology & Systems.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard by CSA Group.

Interpretations: The Strategic Steering Committee on Requirements for Electrical Safety has provided the following direction for the interpretations of standards under its jurisdiction: “The literal text shall be used in judging compliance of products with the safety requirements of this Standard. When the literal text cannot be applied to the product, such as for new materials or construction, and when a

relevant CSA committee interpretation has not already been published, CSA Group's procedures for interpretation shall be followed to determine the intended safety principle."

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This Standard is subject to review within five years from the date of publication, and suggestions for its improvement will be referred to the appropriate committee. The technical content of IEC and ISO publications is kept under constant review by IEC and ISO. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:

- a) Standard designation (number);
- b) relevant clause, table, and/or figure number;
- c) wording of the proposed change; and
- d) rationale for the change.

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**Medical electrical equipment –
Part 2-65: Particular requirements for the basic safety and essential performance
of dental intra-oral X-ray equipment**

**Appareils électromédicaux –
Partie 2-65: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à rayonnement X dentaires intra-oraux**

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL INTRA-ORAL X-RAY EQUIPMENT and its main components, hereafter also called ME EQUIPMENT.

The scope of this standard is restricted to X-RAY EQUIPMENT where the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard

NOTE 1 The X-RAY GENERATOR in DENTAL INTRA-ORAL X-RAY EQUIPMENT always comprises an X-RAY MONOBLOCK ASSEMBLY. Therefore in this particular standard the concept of X-RAY TUBE ASSEMBLY is replaced by that of X-RAY MONOBLOCK ASSEMBLY.

NOTE 2 Main components may be for instance the X-RAY MONOBLOCK ASSEMBLY and an ELECTRONIC X-RAY IMAGE RECEPTOR.

NOTE 3 Photostimulated phosphor plates and their readers (hardware and software) are excluded from the scope of this particular standard, since they have no electrical APPLIED PARTS in the PATIENT ENVIRONMENT, and are not ME EQUIPMENT.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-63, IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45 or IEC 60601-2-43 are excluded from the scope of this particular standard. The scope of this International Standard also excludes RADIOTHERAPY SIMULATORS and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME EQUIPMENT intended to be used for DENTAL RADIOSCOPY.

Within its specific scope, the clauses of this particular standard supersede and replace those of IEC 60601-2-7, *Medical electrical equipment – Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* and of IEC 60601-2-32, *Medical electrical equipment – Particular requirements for the safety of associated equipment of X-ray equipment*.

NOTE 4 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or in this particular standard. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the IEC 60601-1 3rd edition scheme for DENTAL INTRA-ORAL X-RAY EQUIPMENT.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to ME EQUIPMENT in the scope of this International Standard.

¹ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*